Rec'd PCT/PTO 28 FEB 2005

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

RECEIVED
01 SEP 2004
WIPO PCT

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P031652WO/CJM		

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB 03/04194	01.09.2003	30.08.2002

International Patent Classification (IPC) or both national classification and IPC
A61K47/48

Applicant
CHIRON SRL et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

 ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30.03.2004	31.08.2004

Name and mailing address of the international preliminary examining authority:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Bardili, W

Telephone No. +49 89 2399-2132

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/04194

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-19 as originally filed

Claims, Numbers

1-45 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

 These elements were available or furnished to this Authority in the following language: , which is:

 ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

 ☐ the language of publication of the international application (under Rule 48.3(b)).

 ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 ☐ contained in the international application in written form.

 ☐ filed together with the international application in computer readable form.

 ☐ furnished subsequently to this Authority in written form.

 ☐ furnished subsequently to this Authority in computer readable form.

 ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

 ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

 ☐ the description, pages:

 ☐ the claims, Nos.:

 ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

 (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

 ☐ the entire international application,

 ☒ claims Nos. 42 with respect to industrial applicability

 because:

 ☒ the said international application, or the said claims Nos. 42 relate to the following subject matter which does not require an international preliminary examination (specify):

 see separate sheet

 ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

 ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

 ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

 ☐ the written form has not been furnished or does not comply with the Standard.

 ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-45
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-45
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	
	No:	Claims	1-41,43-45

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 42 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

D1/ US-A-5 929 049 discloses polysaccharides modified by masked aldehyde groups as intermediates for the preparation of polysaccharide protein conjugates. The masked aldehyde groups are allyoxy groups introduced into the polysaccharide by an alkylation reaction. They are converted to the free aldehyde by treatment with ozone. The aldehyde functionality so obtained is used to conjugate a peptide or protein to the polysaccharide (see claim 14; example 1).

D2/ WO-A-95 29 927 uses a similar concept for the preparation of aldehyde modified polysaccharides and peptide conjugates thereof. An ethylenically unsaturated carbon chain is attached to the saccharide through a glycosidic bond (see figures 1-8) and may be converted to an aldehyde functionality through ozonolysis.

The modified capsular saccharides according to claim 1 are distinguished from the state of the art in that the linkage between masked aldehyde group and the saccharide backbone is different since it comprises a nitrogen atom instead of oxygen (see claim 1, formula (I), linkage N(R1)-L). The claimed subject-matter is hence novel.

The object of the invention may be seen in the provision of modified capsular polysaccharides which can be conjugated to proteins to obtain vaccines having a high immunogenicity. In the absence of any suggestions in the prior art to modify the linkage between saccharide backbone and protein to solve the above technical problem inventive step is acknowledged.

For the assessment of the present claim 42 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.